



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,491	01/18/2001	Jack L. Arbiser	EU 98055 CON	8772

23579 7590 11/04/2003

PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 11/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,491

Applicant(s)

ARBISER, JACK L.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 10-12 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's petition for supervisory review filed on March 12, 2003 have been considered but the petition has been treated as a response since it is premature.

Applicant's election of species with traverse of curcuminoid in Paper No. 14 is acknowledged. The traversal is on the ground(s) that an election of species requirement, if necessary, should be made in the first Office Action, before a search of the prior art has been conducted and that the Examiner has not cited any source to justify the election of species requirement so late in the prosecution of this application. This is not persuasive because a restriction requirement can be made at any time before final action when the distinctness and independence of the invention is clear and there is a serious burden on the Examiner (MPEP 811). Instant claims are drawn to an astronomical number of compounds with a variety of different moiety of chemical structure without common core. Accordingly, the searching the compounds would place a serious burden on the Examiner especially required non-patent literature search. Therefore, the election of species made on last Office Action is deemed proper and made Final. Claims 10-12, 18 and 19 are being examined since they read on the elected species of curcuminoid. Claims 4-6 and 17 are withdrawn from consideration since they do not read on the elected species.

Claim Rejections - 35 USC § 103

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galardy (U.S. Patent No. 5,696,147), AIAIousi et al. (1996) and Arbiser et al. (June, 1999) in view of Thaloor et al. (1998) of record.

Galardy discloses that conditions including **angiosarcoma** and **Kaposi's sarcoma** benefit from angiogenesis inhibition. (column 14, lines 64-66). Galardy discloses that inhibition of angiogenesis is envisioned as a component of effective treatment of malignancy. (column 2, lines 20-23).

AIAIousi et al. teach on the abstract that basic fibroblast growth factor (bFGF) is a growth factor and an angiogenesis factor which may play a role in the evolution of cutaneous **malignant melanoma**.

Art Unit: 1617

Arbiser et al. (June, 1999) on the abstract, teach that clinical trial of angiogenesis inhibitors in humans with **angiosarcoma** and **hemangioendothelioma** are warranted since angiogenesis inhibitors are highly effective in treatment of angiosarcoma in mice.

The references do not teach a curcuminoid for the treatment of the disorders set forth in claims 10 and 18.

Thaloor et al. teach that **curcumin** inhibits angiogenesis.

It would have been obvious to one of ordinary skill in the art to employ curcumin (curcuminoid) for the treatment of the disorders set forth in claims 10 and 18 because Galardy discloses those conditions (i.e. angiosarcoma, Kaposi's sarcoma) do benefit from angiogenesis inhibition and because the disorders such as malignant melanoma, and hemangioendothelioma are associated with angiogenesis as taught by AIAIousi et al. and Arbiser et al. and because curcumin is an angiogenesis inhibitor as taught by Thaloor et al. One would have been motivated to employ curcumin for the treatment of angiogenesis related disorders set forth in claims 10 and 18 to achieve expected benefit of angiogenesis inhibition by curcumin as taught by Thaloor et al. The utilization of curcuminoid (e.g. demethoxycurcumin) is obvious because curcumin is a product which contains demethoxycurcumin. Absent any evidence to contrary there would have been a reasonable expectation of successfully treating angiogenesis related disorders with angiogenesis inhibitor (i.e. curcumin).

Claims 10, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arbiser et al. (March, 1998) in view of Thaloor et al. (1998) of record.

Art Unit: 1617

Arbiser et al. on the abstract, teach that patients with recessive dystrophic epidermolysis bullosa (RDEB) are suggested to treat with angiogenesis inhibitors. Arbiser et al. also teach that the patients with RDEB have elevated levels of basic fibroblast growth factor (bFGF) and that angiogenesis inhibitors may antagonize the effects of bFGF. Arbiser et al. teach that there are currently no other means of treatment for the disorder, which has a high morbidity and mortality rate.

Arbiser et al. lack curcumin and demethoxycurcumin.

Thaloor et al. teach that curcumin inhibits angiogenesis.


It would have been obvious to one of ordinary skill in the art to employ curcumin or curcuminoid (i.e. demethoxycurcumin) for the treatment of RDEB because Arbiser et al. suggested that angiogenesis inhibitors are effective in treatment of RDEB and because it is obvious to one of ordinary skill in the art that curcumin is a curcuminoids with has a mixture of demethoxycurcumin. One would have been motivated to employ curcumin (mixture of demethoxycurcumin), a well known by Thaloor et al. as an angiogenesis inhibitor, for the treatment of RDEB to avoid death of a patient with RDEB since angiogenesis inhibitors are currently only treatment available for the patients with RDEB disorder, which has a high morbidity and mortality rate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

11/3/03

jmk
October 31, 2003